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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/757,656	01/14/2004	Robert A. Ashley	512-53 DIV	3939
23869 7590 04/23/2007 HOFFMANN & BARON, LLP 6900 JERICHO TURNPIKE SYOSSET, NY 11791			EXAMINER TRAN, SUSAN T	
			ART UNIT	PAPER NUMBER
			1615	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/23/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/757,656

Applicant(s)

ASHLEY, ROBERT A.

Examiner

Susan T. Tran

Art Unit

1615

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 January 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2,24-29,32,34,36,38 and 65-77 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,24-29,32,34,36,38 and 65-77 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim 24 is rejected under 35 U.S.C. 102(e) as being anticipated by Pflugfelder et al. US 6,455,583.

Pflugfelder discloses a method for treating meibomian gland disease associated with rosacea comprising orally administering non-antimicrobial amount of tetracycline such as chemically modified tetracycline (CMT), and other tetracycline compounds (column 4, lines 1-67). The claimed CMT compounds are disclosed in column 5, lines 42-54. CMT compounds are orally administered at a dosage level from about 20% to about 80% of the normal antibiotic therapeutic dose of the particular tetracycline compound being employed (column 5, lines 1-3).

***Claim Rejections - 35 USC § 103***

Claims 1, 2, 24-29, 32 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pflugfelder et al. US 6,455,583, in view of Robinson et al. US 5,260,292.

Pflugfelder teaches a method for treating meibomian gland disease associated with rosacea comprising orally administering non-antimicrobial amount of tetracycline such as chemically modified tetracycline (CMT), and other tetracycline compounds (column 4, lines 1-67). CMT compounds are orally administered at a dosage level from about 20% to about 80% of the normal antibiotic therapeutic dose of the particular tetracycline compound being employed (column 5, lines 1-3). Pflugfelder further teaches long term use of CMT without disturbing the normal microbial flora (column 5, lines 37-42).

Pflugfelder does not explicitly teach the claimed method for treating acne including those recited in claim 2, and acne associated with pustules, papules, or nodules.

Robinson teaches a method and composition for treating acne including acne rosacea (column 1, lines 15-21). Robinson also teaches that acne rosacea is manifested by erythema, telangiectasia, pustules, and papules (column 3, lines 1-60). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Pflugfelder for the treatment of rosacea in view of the teaching of Robinson, because Robinson teaches the overlapping patient population, *i.e.*, acne rosacea is an inflammatory eruption that is chronic and occurs on

the face...the eyes and eyelids are commonly effected (inflammation and infection of the conjunctiva, eyelids, and hypertrophy of the meibomian gland) (column 3, lines 46-55), because Robinson teaches CMTs possess biological activities capable of neutralizing the inflammatory factor, and because Pflugfelder teaches treatment for patients who also have facial rosacea (example 1). Accordingly, it would have been obvious to one of ordinary skill in the art to, by routine experimentation optimize the method of Pflugfelder for the treatment of inflammatory eruption occurs on the face such as rosacea.

Claims 36, 38 and 65-77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pflugfelder et al. US 6,455,583, in view of Ramamurthy et al. US 5,998,390 and Robinson et al. US 5,260,292.

Pflugfelder further does not teach the exact claimed CMT compound as recited in claim 36.

Ramamurthy teaches a composition useful for the treatment of MMP-dependent conditions comprising CMT compound includes 6-demethyl-6-deoxy-4-de(dimethylamino)tetracycline compound (column 7, lines 46-67). Thus, it would have been obvious to one of ordinary skill in the art to select the CMT compound in view of the teaching of Ramamurthy to obtain the claimed invention, because Ramamurthy teaches the use of pharmaceutically known tetracycline compounds such as 6-demethyl-6-deoxy-4-de(dimethylamino)tetracycline, doxycycline, and minocycline, and because Pflugfelder teaches the use of CMT compound.

***Response to Arguments***

Applicant's arguments filed 01/19/07 have been fully considered but they are not persuasive.

Applicant argues that the "Methods of Treatment" of Arbiser, treatments of skin disorders are administered topically or regionally. Accordingly, the obvious rejections over Arbiser have been withdrawn.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-R 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



S. Tran  
Primary Examiner  
Art Unit 1615